REMARKS

The claims are 35-77, with claim 35 and 55 being independent. Claims 1-34 have been cancelled without prejudice or disclaimer. Support for claims 35-39 may be found claims 20 and 32. Support for claims 40-42, 68-69 may be found in the specification at page 2, line 36 to page 3, line 2. Support for claims 43 and 60 may be found at page 5, lines 13-14. Support for claims 44 and 62 may be found at page 4, lines 33-34. Support for claims 45-48, 66-67 and 72-74 may be found at page 3, lines 8-15. Support for claims 49-51 and 57-58 may be found at page 2, lines 31-35. Support for claims 52-54 may be found at page 3, lines 16-18. Support for claim 55 may be found in claims 20 and 28. Support for claim 56 may be found in the specification at page 2, line 29 to page 3, line 2 and Example 7 at page 15. Support for claims 59 and 61 may be found at page 2, lines 26-28. Support for claim 63 may be found in at page 3, lines 6-9 and page 2, lines 26-28 and claim 2. Support for claims 64-65 and 70-71 may be found at page 3, lines 6-7. Support for claim 75-76 may be found in Example 3, at page 10. Support for claim 77 may be found in Example 7, at page 12. No new matter has been added.

Previously pending claims 20-28, 31 and 32 have been found allowable. Claims 29, 30, 33 and 34 were rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite for reciting trademark/trade names for the matrix or coating element. Applicants respectfully submit that this formal objection has been addressed by the new claims presented herein and that these new claims should be interpreted as encompassing the coating or matrix species identified by the trademarks/trade names. For example, it is well known in the art that Eudragit L100-55 and Eudragit RS are methacrylic acid copolymers (See Pformulate and Rohm and Degussa documents in IDS identifying the Eudragits as methacrylic acid copolymers/methacrylate based coatings and Handbook of Pharmaceutical Excipients, 3rd Edition, pg 401-406 document in IDS identifying the Eudragits as polymethacrylates). Accordingly, the generic descriptors "methacrylate" or "methacrylic acid copolymers" in the claims should be interpreted to include Eudragits (specific examples of which are provided in the specification at page 2, lines 31-35, page 3, lines 6-15 and in the Examples).

More specifically, as indicated in the product specifications submitted herewith (Rohm and Degussa information sheets), Eudragit L100-55 is defined in the USP/NF as methacrylic acid copolymer Type C. This US Pharmacopoeia/National Formulary definition has been added to the specification and claims to define Eudragit L100-55. Similarly, the USP/NF definitions of ammonio methacrylic acid copolymer Type A for Eudragit RL, ammonio methacrylic acid copolymer Type B for Eudragit RS and methacrylic acid copolymer dispersion for Eudragit L30

D-55, each of which are have been added to the specification and claims. Because these definitions are US Pharmacopoeia/National Formulary definitions, Applicants respectfully submit that these additions do not constitute new matter.

It is also known that Aquateric is a cellulose acetate phthalate-based coating; Sureteric is a polyvinyl acetate phthalate-based coating and HPMCP-HP-55S is a hydroxypropyl methylcellulose phthalate (See Handbook of Pharmaceutical Excipients, 3rd Edition, pg 99-101, and Pharmaceutical Excipients documents in IDS). The generic descriptors "cellulose acetate phthalate, polyvinyl acetate phthalate, and hydroxypropyl methylcellulose phthalate" present in the claims are intended to encompass the respective species represented by these trademarks/trade names.

It is further known that Methocel K4M is a hydroxypropylmethyl cellulose. (See Handbook of Pharmaceutical Excipients, 3rd Edition, pg 252-255, and USP Dictionary Pharmaceutical Excipients, pg 462, documents in IDS identifying Methocel K4M as a hydroxypropyl methyl cellulose having a nominal viscosity of 4000. Accordingly, the descriptor "hydroxypropyl methylcellulose having a nominal viscosity of 4000" in the amended claims and in the specification should be interpreted to describe Methocel K4M (see specification at page 3, lines 13-15). Applicants respectfully submit that this amendment does not add new matter, as one skilled in the art would know and understand the component identified as Methocel K4M to be a hydroxypropyl methylcellulose having a nominal viscosity of 4000.

For the avoidance of doubt, Applicant notes that, as set forth in the specification, "5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione" (or "Compound (I)") may exist in one of several tautomeric forms, as individual tautomeric forms or as mixtures thereof, all of which are encompassed by the terms "Compound (I)" or "5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione". Furthermore, 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione contains a chiral atom, and therefore can exist in up to two stereoisomeric forms. The term "5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione" (or "Compound (I)") also encompasses all of these isomeric forms, whether as individual isomers or as mixtures of isomers, including racemates. See the specification at page 5, lines 26-31. Accordingly, when reference is made to "Compound (I)", or to "5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione", or to "5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, or a tautomer thereof", or to "said 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione ", all tautomeric and isomeric forms of the compound are intended to be encompassed.

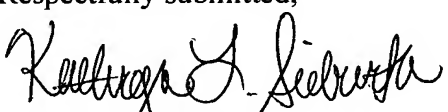
Additionally for the avoidance of doubt, as set forth in the specification, when reference is made to scalar amounts, including mg amounts and % weight amounts, of "5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, or a tautomer thereof, in a pharmaceutically acceptable form", the scalar amount referred to is made in respect of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione per se: for example, 2 mg of Compound (I), or 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, in the form of the maleate salt is that amount of maleate salt which contains 2 mg of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione (not: 2 mg of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione maleate salt). See the specification, page 7, lines 11-16.

In view of the foregoing, Applicants respectfully submit that the subject application is in condition for allowance. If the Examiner has any objections or concerns, the Examiner is respectfully requested to contact Applicants' undersigned attorney to resolve such issues and advance the case to issue.

An Information Disclosure Statement is being filed herewith.

This Amendment is being filed together with a Petition for Extension of Time. In the event that these papers get separated or there is any deficiency in the Petition, this constitutes a Petition for Extension of Time for the minimum period required to effect timely filing of this Amendment, together with an authorization to charge any fees under 37 C.F.R. §1.16 or §1.17 which may be required by this paper to Deposit Account No. 19-2570.

Respectfully submitted,



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